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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,843	12/02/2003	Hans Kurt Pingel	6207.520 -US	3225

23650 7590 12/01/2005

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,843	PINGEL ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-24 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17 and 22, drawn to a method for large-scale production of Factor VII, classified in class 435, subclass 69.1.
- II. Claims 18-19, drawn to a Factor VII polypeptide, classified in class 435, subclass 226.
- III. Claims 20 and 21, drawn to a composition comprising a plurality of Factor VII polypeptides, classified in class 435, subclass 226.
- IV. Claims 23 and 24, drawn to a method of treatment using a Factor VII polypeptide, classified in class 424, subclass 94.64.

For each of Inventions III and IV above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-IV and if, III or IV is elected, one of Inventions (A)-(O), as indicated.

If Invention III is elected, elect one of:

(A) The percentage of the oligosaccharide chains having a neutral charge, wherein the percentage of oligosaccharide chains of serum-free Factor VII having a neutral charge is lower than that of serum-raised Factor VII and higher than that of native Factor VII;

(B) The percentage of the oligosaccharide chains comprising at least one terminal galactose residue, wherein the percentage of oligosaccharide chains of serum-free Factor VII

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having a at least one terminal galactose residue is lower than that of serum-raised Factor VII and higher than that of native Factor VII;

(C) The percentage of the oligosaccharide chains comprising at least one terminal N-acetylgalactosamine residue, wherein the percentage of oligosaccharide chains of serum-free Factor VII having a at least one terminal N-acetyl galactose residue is lower than that of serum-raised Factor VII and higher than that of native Factor VII;

(D) The percentage of the oligosacchalide chains comprising at least one uncapped antenna, wherein the percentage of oligosaccharide chains of serum-free Factor VII comprising at least one uncapped antenna is lower than that of serum-raised Factor VII and higher than that of native Factor VII;

(E) A specific combination of (A)-(D).

If Invention IV is elected, elect one of:

(F) haemophilia A;

(G) haemophilia B;

(H) Factor XI deficiency;

(I) Factor VII deficiency

(J) Thrombocytopenia;

(K) von Willebrand's disease;

(L) presence of a clotting factor inhibitor;

(M) surgery;

(N) trauma;

(O) anticoagulant therapy.

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Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

Inventions II and III are distinct because the products of Inventions II and III are physically and functionally distinct chemical entities.

Inventions (A)-(D) are distinct because the products of Inventions (A)-(D) are physically and functionally distinct chemical entities.

Inventions I and IV are independent because the methods of Inventions I and IV comprise different steps, utilize different products and/or produce different results.

Inventions (E)-(O) are independent because the methods of Inventions (E)-(O) comprise different steps, utilize different products and/or produce different results.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The inventions are distinct because the polypeptide can also be made by chemical synthesis.

The method of Invention IV is related to the polypeptide of Invention II as a product and process of using. The inventions are distinct because the polypeptide can also be used for making an antibody.

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Inventions I and III are unrelated because the method of Invention I neither uses the product of Invention III nor makes said product.

Inventions III and IV are unrelated because the method of Invention IV neither uses the product of Invention III nor makes said product.

A search for more than one of Inventions I-IV would be a burden on the Office for the following reasons.

Because the products of Inventions II and III are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching both of Inventions II and III would be a burden on the Office.

Because the products of Inventions (A)-(D) are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions (A)-(D), or a subset thereof would be a burden on the Office.

Because the methods of Inventions I and IV comprise different steps, utilize different products, and/or produce different results, a search for one said invention would not encompass a search for any other invention and searching all of Inventions I and IV, or a subset thereof would be a burden on the Office.

Because the methods of Inventions (E)-(O) comprise different steps, utilize different products, and/or produce different results, a search for one said invention would not encompass a search for any other invention and searching all of Inventions (E)-(O), or a subset thereof would be a burden on the Office.

A search for the products of Inventions II and III would not encompass a search for the methods of Inventions I and IV, or vice versa, because said methods are not the only methods of

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making and/or using said products. Thus, a search of any of Inventions II and III with any of Inventions I and IV would be a burden on the Office.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Restriction between product and process claims has been required. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re Ochiai*, and *In re Brouwer*). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

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SHERIDAN SWOPE, Ph.D.
PATENT EXAMINER